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10/786,727	02/25/2004	Joseph L. Mark	65937-0045	2729

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EXAMINER

APANIUS, MICHAEL

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/786,727

Applicant(s)

MARK, JOSEPH L.

Examiner

Michael Apanius

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: at paragraph 29, line 3, it appears that "FIG. 2" should be --FIG. 1A--; and at paragraph 45, line 10, it appears that "fluid source 28" should be --fluid source 65--. Appropriate correction is required.

### ***Claim Objections***

2. Claims 6 and 19 are objected to because of the following informalities: at line 2 of these claims, it appears that "needless" should be --needleless--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9, 10, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It not clear whether the comparisons to a vacuum are in relation to the amount of vacuum created or to the pressure resulting from the created vacuum. For example, "the cracking pressure is less than or equal to a vacuum" could mean that the cracking pressure only equals a lesser vacuum which

creates a larger pressure. Alternatively, the limitation could mean that the cracking pressure is less than the pressure resulting from the created vacuum.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-8 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Privatera et al. (US 6,273,862) in view of Moore (US 2,866,457).

7. Privatera discloses a biopsy system comprising a vacuum assisted biopsy device that communicates saline (column 18, 1<sup>st</sup> paragraph; column 21, lines 9-13) and/or an anesthetic (column 21, lines 14-16) to a piercer (70). However, Privatera does not expressly disclose a fluid connector including two check valves configured to provide the two fluids in communication with the biopsy device.

8. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39). The fluid connector includes two check valves (9, 22) for providing fluid communication from one of two fluid sources (6, 26) to an output of the fluid connector.

9. In regards to claim 2, Privatera and Moore do not expressly disclose a duckbill valve member. However, Moore does state that any check valve well known in the art can be used. Applicant states that a duckbill-style valve is well known (paragraph 40).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a duckbill valve member as is well known in the art in place of the valve member of Moore because it is routine in the art to substitute alternative parts.

10. In regards to claims 3 and 4, the check valves comprise resiliently compressible valve members (around and including spring 25 in figure 1) secured in a valve seat (around 25 in figure 1).

11. In regards to claims 5-7, Privatera discloses the use of an isotonic solution (saline) and an anesthetic as noted above. Moore teaches the use of a bag (6) and a needleless syringe (26) for holding fluids.

12. In regards to claim 8, the check valves taught by Moore inherently have a predetermined cracking pressure.

13. The limitations of claims 14-21 are met as noted above.

14. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the fluid connector taught by Moore in the system of Privatera in order to simplify and save time in surgical procedures by avoiding the need to change fluid connections and to manually open and shut valves.

15. Claims 11, 13, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Privatera et al. (US 6,273,862) as modified by Moore (US 2,866,457), as applied to claims 1-8 and 14-21 above, and further in view of Turturro et al. (US 6,331,165).

16. Privatera as modified by Moore does not expressly disclose luer fittings.

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17. Turturro teaches luer fittings (column 18, lines 33-41) for the purpose of providing quick and easy connection and disconnection. Furthermore, male and female luer fittings are well known in the art and routinely used.

18. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used luer fittings as taught by Turturro and as are well known in the art to make the connections of Privatera as modified by Moore in order to provide a quick and easy means to connect and disconnect the fluid sources to the check valves.

19. Claims 1-10, 12, 14-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 2002/0082519) in view of Moore (US 2,866,457).

20. Miller discloses a biopsy system comprising a vacuum assisted biopsy device, a first fluid source (400 in figure 12), and a fluid connector (around 402) configured to provide the first fluid source in communication with the biopsy device and including a check valve (402). Miller further discloses the use of a second fluid source (paragraph 90; "anesthetic"). However, Miller does not expressly disclose a second check valve configured to provide the second fluid source in communication with the biopsy device.

21. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39). The fluid connector includes two check valves (9, 22) for providing fluid communication from one of two fluid sources (6, 26) to an output of the fluid connector.

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22. In regards to claim 2, Miller and Moore do not expressly disclose a duckbill valve member. However, Moore does state that any check valve well known in the art can be used. Applicant states in the specification that a duckbill-style valve is well known (paragraph 40). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a duckbill valve member as is well known in the art in place of the valve member of Moore because it is routine in the art to substitute alternative parts.

23. In regards to claims 3 and 4, the check valves comprise resiliently compressible valve members (around and including spring 25 in figure 1) secured in a valve seat (around 25 in figure 1).

24. In regards to claims 5-7, Miller discloses the use of an isotonic solution (saline; paragraphs 141-144) and an anesthetic. Moore teaches the use of a bag (6) and a needleless syringe (26) for holding fluids.

25. In regards to claim 8, check valves inherently have a predetermined cracking pressure.

26. In regards to claim 9, Miller discloses that the cracking pressure is less than or equal to a vacuum created in the fluid connector by the biopsy device (paragraph 143).

27. In regards to claim 10, Moore teaches that it is desirable to keep the two fluid sources isolated and that fluid can not pass the check valves in a wrong direction (column 2, lines 15-18). Therefore, the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source.

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28. In regards to claim 12, Miller discloses drawing a predetermined amount of fluid from a fluid source (paragraph 142).

29. The limitations of claims 14-23 and 25 are met as noted above.

30. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the fluid connector taught by Moore in the system of Miller in order to simplify and save time in surgical procedures by avoiding the need to change fluid connections and to manually open and shut valves.

### ***Conclusion***

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Banko (US 3,844,272), Clement (US 5,335,671), Schechter et al. (US 5,403,276) and Tal et al. (US 5,868,785) disclose various vacuum assisted, irrigated biopsy devices. Gerlach et al. (US 6,197,005) discloses a Y-piece with check valves.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

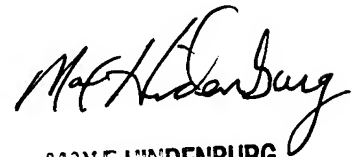
33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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